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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,406	03/29/2006	Bernadette Verneau	065691-0397	3436

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EXAMINER	
ML, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,406	VERNEAU, BERNADETTE	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,14-23 and 26-34* is/are pending in the application.

4a) Of the above claim(s) *15,16,23 and 26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,14,17-22,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/09 has been entered.

Applicant's amendment in the reply filed on 3/12/09 is acknowledged, with the cancellation of Claims 2-13, 24, and 25. Claims 1, and 14-23, and 26-34 are pending. Claims 15, 16, 23, and 26-32 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 1, 14, 17-22, 33, and 34 are examined on the merits**.

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 14, 17-22, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 17 recite the limitation "the form" in lines 9 and 2, respectively. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites "wherein the composition is in the form of soft or hard capsules" in lines 9-10. However, no "form" was mention was mentioned up to this point, thus it is not clear what "form" Applicant is referring to.

Claim 1 recites "said formulation base comprises at least one vegetable and/or mineral oil selected from soya oil, sunflower oil, corn oil, olive oil, nut oil, and a liquid paraffin, and at least one lipophilic additive selected from polyethylene glycol, beeswax, candelilla wax, carnauba wax, polyethylene oxide wax, petroleum wax, and glycerol palmitostearate, **which** is solid or pasty at room temperature...", it is unclear what "which" is referring to, is it the "formulation base"? the "lipophilic additive"? or "glycerol palmitostearate"?

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 14, 17-22, 33, and 34 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Mann (US 5,273,754), Horrobin (US 4,393,049), Mamana (US 2002/0192308), and Williams et al (US 6,069,147).

This is a new rejection necessitated by the Applicant's amendment filed on 3/12/09.

Mann teaches an appetite suppressant composition leading to a decrease in weight (col 1, lines 5-10) comprising a heating carminative substance, such as standard oleoresin capsicum which contains capsaicin (thus capsaicinoids) (thus in the form of capsicum resin) (col 2, lines 45-50). Mann also teaches that capsaicin is a preferred heating carminative substance, ...having a gastric heating effect exhibits a local anesthetic effect in the stomach (particularly upon the gastric nerves controlling hunger) when administered orally at a sufficient dose (col 2, lines 30-40). Mann further teaches that the appetite suppressant composition in a form suitable for oral administration, and preferably as a capsule (thus solid or pasty at room temperature) (col 4, lines 22-28). Mann also teaches a 60 mg out of 300 mg capsule of menthol (thus 20% other physiologically active component).

Mann does not teach the incorporation of vegetable oils (sunflower oil), green tea, and lipophilic additive into the composition, and neither does Mann teaches the claimed amount of the components, or the claimed other physically active components.

Horrobin teaches the treatment of obesity involves the administration of linoleic acid, generally in the form of vegetable oils such as sunflower oil and/or corn oil (col 3, lines 30-35). Horrobin also teaches the composition as administrated is in the form of a capsule, etc (col 6, lines 30-38).

Mamana teaches an appetite suppressant for controlling weight comprising green tea or green tea leaf extract (thus one or more physiologically active components) (claim 1). Mamana further teaches that the appetite suppressant is preferably administered orally in the form of a capsule etc (thus solid or pasty at room temperature) [0014].

Williams et al teach thermogenesis stimulating drugs during or following a weight loss diet (see Abstract). Williams et al teach excipients and/or additives can contain the usual diluents such as water, oil and/or suspending aids such as polyethylene glycols (thus a lipophilic additive, thus is solid or pasty at room temperature) and the like (col 2, lines 60-68; col 3, lines 1-10).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for weight control. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for weight control.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for weight control. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re* Sussman, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior

art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because they have the ability for weight control, which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Mann, Horrobin, Mamana, and Williams et al since all of them teach compositions for weight control individually in the art. Since all the compositions yielded beneficial results in weight control, one of ordinary skill in the art would have been motivated to make the modifications to combine the teachings of the references together. Regarding the limitation to the amount of the components in the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the body weight, age, and appetite of the patient that is needed.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments, regarding Mann does not teach vegetable oil and lipophilic additive in amended claims (page 6, last two paragraphs); Hosoya does not teach lipophilic additive that is solid or pasty at room temperature (page 7; page 8, 1-4 paragraphs); Mamana does not teach soya oil (page 8, last paragraph; page 9, 1-4 paragraphs) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Horrobin, and Williams et al.

Applicant argues that page 11 of the Specification indicates the surprising results.

This is not found persuasive. The allegedly surprising result on Page 11 does not commensurate with the scope of what is being claimed. As 5% beeswax/glycerol palmitosterate is not required in the instant claims, beeswax and glycerol palmitosterate are only among the Markush group of lipophilic additive in amended claim 1. Thus, the allegedly surprising result is not insufficient to overcome the 103 obviousness rejection.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655